REMARKS

Claims 38, 39, 41, 42, 44, 49, 51, 52 and 54-68 are pending in the instant application. Claims 40, 46, 47 and 50 have been canceled, herein. Applicants reserve the right to pursue the subject matter of these claims in a continuing or divisional application. Claims 38, 41, 44, 49, 51 and 54, have been amended. Support for the amendments to these claims can be found throughout the specification for example from page 4, line 29 to page 5, line 2 of the instant specification, Figures 1-4 and in canceled claims 40 and 50. Claims 65-68 have been added. Support for these claims can be found, for example, page 3, lines 1-5 of the instant specification and claims 61-64 as previously presented. No new matter has been added.

Claim Rejections

Rejections under 35 U.S.C. § 102.

The Examiner has rejected claims 38, 39, 43, 44, 49, 54-56, 60 and 61 under 35 U.S.C. § 102(b) as being anticipated by Williams *et al.* WO 97/02045 ("Williams"). Claim 43 has been canceled, rendering this rejection moot as it applies to this claim. The Applicants respectfully traverse.

Under §102, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.1987). Applicants request reconsideration and withdrawal of the rejection.

To facilitate prosecution, Applicants have amended claims 38 and 49 to take on the limitations of canceled claims 40 and 50. Claims 40 and 50 were not rejected as anticipated over the teachings of Williams and thus, claims 38 and 49 as currently amended cannot be deemed anticipated by the teachings of Williams. Nor can their dependent claims 39 and 44.

Moreover, Williams cannot anticipate claims 54-56, 60 and 61. Williams does not teach the administration of between 50 and 100 µg of EtxB. This limitation is a part of all of claims 54-56, 60 and 61. Thus, Williams does not teach each and every limitation of claims 54-56, 60 and 61 and cannot anticipate them.

Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner has also rejected claims 38-44, 46-47, 49-52 and 54-64 under 35 U.S.C. § 102(b) as being anticipated by Hazama *et al*. Immunology 78:643-649 (1993) ("Hazama"). Claims 40, 46, 47 and 50 have been canceled, rendering this rejection moot as it applies to these claims. Applicants respectfully disagree.

The Applicants would like to reiterate that the instant claims recite that EtxB and an antigen, that are a vaccine in combination, are co-administered. In contrast, Hazama only teaches the co-administration of t-gD with EtxB which do not form a vaccine. This is evident, for example, from data summarized in Tables 2 and 4 of Hazama. The Examiner asserted, on page 11 of the Office Action, that the instant specification teaches that glycoproteins of HSV are vaccines against HSV-1 infectious agents. The Examiner alleged that the specification teaches that t-gD, itself, is a vaccine against HSV infections on pages 33-37, in Examples 1, 4 and 7 of the specification. The Examiner is mistaken. Example 1 of the instant specification teaches that the co-administration of EtxB with HSV-1 glycoproteins increased antibody levels, caused T-cell proliferation and a decrease in viral shedding. Example 4 of the instant specification teaches that the co-administration of EtxB with HSV-1 glycoproteins increased antibody levels. Example 7 of the instant specification teaches that the co-administration of EtxB with HSV-1 glycoproteins increased antibody levels, caused T-cell proliferation and a decrease in viral shedding. Nowhere in the specification is tg-D mentioned as a vaccine, either alone or in combination with EtxB. Nowhere in the specification is it taught that all HSV glycoproteins are vaccines. As shown in Hazama t-gD is not a vaccine. While, as indicated by the Examiner, Hazama teaches mucosal and systemic antibody response elicited by administration of certain immunizations, tg-D injected alone does not cause any immune response. Moreover, Hazama teaches that the combination of tg-D and EtxB is not protective against HSV challenge. Thus, t-gD is not a vaccine.

Further, the Examiner contends that "[T]he claims also state that the vaccine is an antigen. An antigen is defined as a molecule that sometimes stimulates an immune response. Thus, all the molecules of Hazama et al., meet the limitations of the claims" (Office Action, page 12). Applicants respectfully assert that this argument is irrelevant regarding this rejection. The term "antigen" as used in claims 38, 39, 41-44, 46 and 47 necessarily refers to antigens that are vaccines when combined with EtxB. While tg-D is an antigen, it is not a vaccine, as discussed

above. Because tg-D is not a vaccine, tg-D cannot be properly relied upon to satisfy this element of the claims. Accordingly, Hazama cannot anticipate claims 38, 39, 41-44, 46 and 47

Moreover, Hazama cannot anticipate claims 54-64. Hazama does not teach the administration of between 50 and 100 μg of EtxB. This limitation is a part of all of claims 54-64. Thus, Hazama does not teach each and every limitation of claims 54-64 and cannot anticipate them.

Applicants request reconsideration and withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, first paragraph.

The Examiner has also rejected claims 38-44, 46-47 and 49-52 under 35 U.S.C. § 112, first paragraph, for lack of written description for adding new matter to the claims. The Examiner argues that there is no support for "enhancing the leukocyte mediated immune response" and for "enhancing a B and T cell lymphocyte mediated immune response". Applicants have canceled claims 40, 46, 47 and 50, rendering this rejection moot as it regards these claims. Applicants respectfully traverse this rejection.

The Applicants have amended claims 38 and 49 from which claims 39, 41-44 and 50-52 depend to specify that the enhancement is in comparison to leukocyte mediated response or B and T cell lymphocyte mediated response when EtxB alone is administered. Support for this amendment is shown in Figures 1-4 and their explanation throughout the specification. Applicants respectfully request that this rejection be withdrawn.

Claim objections.

The Examiner has objected to claims 38 and 40-42 under 37 CFR 1.75(c) as being allegedly improper dependent form for failing to further limit the subject matter of a previous claim. In view of amendments to claims 38 and 49, which recite administration of viral antigen, this objection is moot and should be withdrawn.

CONCLUSION

Applicants submit that the claims as here amended put the application in condition for allowance, and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is invited and encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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